

# Articles

## Postnatal Human Immunodeficiency Virus Antibody Testing The Effects of Current Policy on Infant Care and Maternal Informed Consent

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Routine human immunodeficiency virus (HIV) antibody screening of umbilical cord blood identifies neonates at risk for HIV infection but may hold risks as well as benefits for infants and mothers. We describe the effect of testing on infant placement and care and report the women's understanding of pretest counseling and consent. In a case-control analysis of 327 tested infants, seropositive infants (13) had a higher rate of discharge to home (62%) than did controls (31%). More case infants (100%) received follow-up care and vaccinations than control infants (46%). Of 32 women interviewed after HIV antibody test informed consent, only 31% understood that a positive cord blood test result was inconclusive for the infant, and most (78%) did not identify any associated socioeconomic risks. Most (88%) stated an interest in learning their serostatus, but only 22% returned for test results. Despite the benefits of HIV antibody testing of at-risk infants, current testing and counseling procedures inadequately inform women, limiting the testing benefits to them.

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Perinatally acquired human immunodeficiency virus (HIV) affects an increasing number of women and children.<sup>1</sup> In 1989, an estimated 6,079 infants were born to HIV-infected women in the United States.<sup>2</sup> Because 80% of HIV-positive women are of reproductive age, testing is occurring with increasing frequency in obstetric and neonatal settings. In 1985 the Centers for Disease Control (CDC) recommended maternal HIV antibody testing for women living in high-prevalence areas who have a significant risk of infection, including a history of transfusion, sexual risk factors, and intravenous drug use.<sup>3</sup> Although targeted HIV testing based on epidemiologic research may represent the most practical use of the limited resources available for testing, some groups have called for an HIV screening policy for all pregnant women and newborns.<sup>4-6</sup> Most health care professionals believe that a knowledge of maternal serostatus may enhance perinatal health care through appropriate HIV prevention counseling, therapeutic abortions, access to continuity of care focused on HIV-related illnesses, and early prophylactic and therapeutic interventions for women and their infants.<sup>7-8</sup> Since 1987, San Francisco General Hospital Medical Center has used a policy of targeted, voluntary HIV antibody testing of at-risk pregnant and postpartum women in this high-prevalence population.

While the CDC's policy primarily targets pregnant women with HIV risk factors, a substantial number of urban pregnant women at risk for HIV infection receive little or no prenatal care, precluding serostatus determination before they give birth. Consequently, the first opportunity to screen these women may be at delivery or in the immediate postnatal period. The benefits of postpartum HIV-antibody screening include early zidovudine therapy and *Pneumocystis carinii* pneumonia prophylaxis for the women and early disease de-

tection and treatment in their infants. Postpartum screening, however, raises concerns that have been articulated about HIV testing in other populations—loss of housing, employment, and insurance and compromised medical care access, child care, and family support (S. Katz, "Driving the Sick Underground: HIV Testing—A Phony Cure," *The Nation*, May 28, 1990, pp 738-742)<sup>9,10</sup>—but in a group particularly at risk for discrimination due to race and poverty. Compounding these factors, a positive maternal or neonatal HIV-antibody test provides inconclusive information about the infant's long-range condition; indeed, only 25% to 35% of these newborns remain seropositive at 15 months of age.<sup>11,12</sup> The risks remain unexplored and unquantified, yet the arguments for testing have become more vehement with the rising HIV seroprevalence in women of childbearing age and the demonstrated benefits of early HIV therapy and prophylaxis.<sup>13</sup>

Practitioners of perinatal care are familiar with the difficult balance among their own values, a woman's rights, public health interests, and infants' well-being and rights.<sup>14,15</sup> In California, the legal requirement for informed consent for the cord blood HIV-antibody test has brought conflicts among these parties into the open. Just as for other newborn procedures, the clinician must consider the parent as a proxy for the infant. The woman, in turn, must weigh the test's risks and benefits for both herself and her newborn. Her decision is based on her understanding of complex medical and social issues and of the testing procedure and results.

To assess the actual consequences of the current HIV-antibody counseling and testing in the newborn nursery, we studied two aspects of HIV-antibody screening. Infants identified as seropositive over a two-year period were compared with seronegative control infants matched for race, mater-

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# ABBREVIATIONS USED IN TEXT

AIDS = acquired immunodeficiency syndrome  
 BAPAC = Bay Area Perinatal AIDS Center  
 CDC = Centers for Disease Control  
 HIV = human immunodeficiency virus

nal risk factors, and maternal age to determine whether a positive cord blood test affects an infant's disposition and subsequent medical care. We also used an open-ended questionnaire to evaluate women's understanding of clinicians' informed consent counseling and risk and benefit disclosure for HIV-antibody testing. This questionnaire evaluated the women's understanding of the test's significance, their ability to recall disclosed benefits and risks, their motivations for consenting to the test, and their intentions to return for results. In addition, we documented whether the study group women actually returned for the follow-up appointment for after-test counseling and results. An assessment of the effects of a positive HIV test on the health care, psychosocial factors, and economic status of the women is the subject of a third study currently under way.

## Population and Methods

### Background—Seroprevalence Study

Beginning in 1988, routine care of recently delivered women ( $n = 3,753$ ) included a standardized risk assessment to identify those at risk for HIV infection. At least one medical or social risk factor for HIV infection was identified in 345 women after delivery. Due to oversight or practical constraints, 38 women were not approached before discharge from the hospital; however, these women did not differ significantly from the study women with respect to demographics or risk factors. The remaining 307 were approached by nursery staff or their attending physicians for written informed consent for cord blood serologic testing; 279 (91%) agreed to the test, and 269 were actually tested. Of those, 13 (5%) had positive HIV-antibody cord blood tests.

Our nursery's HIV-antibody informed consent protocol specified that the women would be provided with information about the test's purpose, its risks and benefits, and the significance of a negative or positive result for a woman and her infant. The clinician described alternatives and emphasized the voluntary nature of the test. A follow-up clinic appointment for the woman was made, and she was given a slip with the time, day, and location where she should return for results and counseling. All research procedures were approved by the University of California at San Francisco Committee for Human Research.

### Effects of Postnatal HIV-Antibody Testing on Infant Disposition and Care

The 13 newborns defined as case infants had a positive enzyme-linked immunosorbent assay test using cord blood that was confirmed by Western blot. Maternal race distribution included nine African Americans, three whites, and one Hispanic. Maternal age ranged from 24 to 40 years. Of the 13 infants, 10 showed signs of neonatal drug withdrawal; 8 were either premature or small for gestational age. Two died before age 15 months, one of HIV-related illness. Three infants are now symptomatic with HIV-related illnesses. Of the 13 cases, 7 have seroreverted, and 1 infant has an indeterminate serostatus.

Control infants were retrospectively selected from the 256 infants with negative cord blood tests during the same study period. They were matched for maternal race, age, and five social risk factors: drug use, history of child neglect or abuse, psychiatric history, homelessness, and other risk factors such as incarceration. Of 13 control infants, 10 experienced neonatal drug withdrawal; 6 were either premature or small for gestational age. With the exception of a gastrointestinal operation in one case infant, the case and control groups required only routine neonatal care. Table 1 compares mean

TABLE 1.—Birth Weight, Gestational Age, and Apgar Scores for Case and Control Infants

Measurement	Infants		P
	Case $\bar{x} \pm SD$	Control $\bar{x} \pm SD$	
Birth weight, grams...	2,320.8 $\pm$ 744.3	2,770.0 $\pm$ 533.0	> .05
Gestational age, wk...	36.1 $\pm$ 2.98	38.4 $\pm$ 2.77	> .05
Apgar test score			
1 Min. ....	7.3 $\pm$ 2.02	7.4 $\pm$ 1.32	> .1
5 Min. ....	8.6 $\pm$ 0.75	8.7 $\pm$ 0.48	> .1

birth weights, gestational ages, and Apgar scores of case and control infants. Although case infants tended to have smaller birth weights and lower gestational ages, this difference was not statistically significant given the sizes of the two groups.

To evaluate the effects of a positive HIV-antibody test on the infant, we measured the proportion of control and case infants discharged to three possible locations: home, extended family, or foster care. In addition, we evaluated follow-up health care after discharge by comparing the frequency of vaccinations and continuity of care in the two groups.

### Women's Comprehension of Informed Consent and Test Counseling

During two months of 1990, 33 women identified as having HIV risk factors and who consented to HIV testing were interviewed. These women were referred to one of the study investigators (J. C. P. or P. L.) after consenting to HIV testing and before cord blood test results were returned. Of these, 32 agreed to participate as interview research subjects. Of the 32 women interviewed, 7 had undergone prenatal screening and were shown to be HIV-negative; they were retested at delivery to address the possibility that the initial negative test reflected a recent infection. The racial demographics and socioeconomic status of the interviewed mothers reflected the distribution of the entire study population.

Women were asked to participate in the study within 48 hours of counseling and informed consent for cord blood testing. The interview was designed to evaluate the critical components of information transfer (Table 2); open-ended questions were asked in a neutral, nonleading fashion to prevent systematic response bias. All responses were recorded and then assigned to content categories. When women provided more than one answer for a given question, all responses were recorded. Interview responses have been reported as percentages of total answers to that question. Attendance or nonattendance of subjects at a scheduled outpatient counseling appointment after testing was documented.

**TABLE 2.—Interview to Assess Maternal Understanding of HIV-Antibody Test Informed Consent**

What was the purpose of the cord blood test?  
 Why did you agree to have the test done?  
 What were the test's risks and benefits for you and your baby?  
 What would a positive and negative test mean for both you and your infant?  
 Did hearing or thinking about the test upset or worry you at all?  
 Do you intend to come back to find out the test results? Why or why not?

HIV = human immunodeficiency virus

## Results

### *Effects of Seropositivity on Newborn Disposition and Care*

Seropositive newborns were discharged to their parents more frequently than their seronegative counterparts were. Of the 13 HIV-positive infants discharged from the nursery between 1988 and 1990, 8 (62%) went home with a parent, 2 to extended family, and 3 to foster care. Of the matched control infants, four (12%) were discharged to parents, six to extended family, and three to foster care. Because the number of case and control infants was small, the difference in the rate of discharge home with parents was not statistically significant ( $P = .12$ ).

The seropositive infants received more complete follow-up care than did the control infants. All case infants received appropriate follow-up care and vaccinations, in contrast to only 6 (46%) of 13 control infants ( $P < .01$ ). Of the 13 case infants, 9 were observed by the Bay Area Perinatal AIDS [acquired immunodeficiency syndrome] Center (BAPAC), a treatment and research group established for children and their families who are at risk for HIV infection, 1 was placed in a foster care program for infants with special medical needs, and the remaining 3 were cared for by private physicians.

### *Maternal Comprehension of Test Purpose and Result Significance*

Most women understood that they had given permission for an HIV-antibody test but did not understand its clinical implications. Of the 32 women, 2 (6%) could not recall the purpose of the cord blood test. Only 6 (19%) thought that the HIV test evaluated their own serostatus; 13 (41%) thought that the test was only for the infant, and 11 (34%) thought it reflected the status of both mother and infant.

Most of the women appeared to understand the general concept of vertical transmission; however, 13 (41%) cited reasons other than "wanting to know if I have AIDS/HIV or the baby has AIDS/HIV" as the reason they consented to testing. These additional motivations for consenting to the test ranged from acquiescence to the physician's or a parent's authority (16%) ("the doctor/my mom wanted me to") to confirmation of negative prenatal tests (22%).

Confusion about the implications of a positive test result for both the woman and her baby was prevalent. Of the 32 women, 22 (69%) viewed a positive result as an indication that the mother was either infected with HIV or had AIDS. Eleven mothers (34%) thought that a positive test meant the baby had AIDS, and another five (16%) said the baby would be infected with HIV. Only 10 women (31%) knew that a positive test only indicates a risk factor for infection in the

baby and that the baby would require later testing. Further, 6 of the 9 women (67%) counseled by an attending physician understood the test's medical meaning, but only 4 of the 23 women (17%) counseled by house staff did so.

Despite the disclosure of risks (such as lack of confidentiality and loss of housing, insurance, and work), which is a component of the informed consent protocol, these women recalled few risks associated with the test for either themselves or their infants (Table 3). Of the nine women coun-

**TABLE 3.—Maternal Understanding of HIV-Antibody Test Risks and Benefits**

Maternal Response	Personal, n = 32 (%)	Infant, n = 32 (%)
<b>Risks</b>		
None.....	25 (78)	28 (88)
1 or more.....	7 (22)	4 (12)
Stress or other's knowledge...	5 (16)	0 (0)
Socioeconomic.....	1 (3)	0 (0)
Unclear.....	3 (9)	4 (12)
<b>Benefits</b>		
None.....	8 (25)	8 (25)
1 or more.....	24 (75)	24 (75)
Early treatment.....	18 (56)	18 (56)
"Just knowing".....	10 (31)	10 (31)
Other.....	1 (3)	1 (3)

HIV = human immunodeficiency virus

seled by the attending physician, six (67%) could identify at least one risk, compared with only one (4%) of those counseled by house staff. In keeping with previous studies on informed consent in other settings, our population had a better understanding of test benefits than of risks.<sup>16,17</sup>

The women's responses to the HIV cord blood test were varied. Most thought that having an HIV test was not stressful, and most stated an interest in knowing their own serostatus. In all, 19 study subjects (59%) reported no stress and 10 (31%) indicated only mild stress when discussing the test or waiting for results. Only three women (9%) reported moderate to high stress related to the cord blood test. Most women (28; 88%) said they intended to come back for the results. Only three women (9%) indicated that they would not return because they felt certain the test would be negative, and one woman said that she just did not want to know the result. Despite the frequency of a stated desire to know the test results, only seven women (22%) returned for scheduled appointments in the hospital clinic to obtain these results.

## Discussion

In this study population, a determination of HIV seropositivity was associated with a higher rate of discharge home with parents and better medical care for infants. Confusion about the meaning of a positive test result and the low return rate to learn test results, however, may limit the effects of testing as a means of improving health care and preventing HIV transmission. Special care must be taken to verify that the counseling and testing procedures maximize benefits for both women and their infants.<sup>18</sup>

### *Perinatal HIV-Antibody Testing—What Does It Mean for the Newborn?*

Testing for the HIV antibody in the nursery is best undertaken in the context of a comprehensive, multidisciplinary

treatment and counseling program for both the infants and their mothers.<sup>19,20</sup> Although many health care institutions have developed HIV testing policies designed to meet these goals, testing programs vary widely among hospitals. The successful follow-up seen in this group indicates the possible benefits of targeted HIV testing in a model perinatal care program. In our study population, most case infants and their families became enrolled in HIV research and treatment programs through BAPAC. Because the women and infants were observed as pairs, BAPAC was able to provide psychological, medical, and social services aimed at meeting the needs of both the women and their infants. BAPAC provided follow-up of women who did not return for test results, as well as reimbursing them for child care and transportation expenses, a virtual necessity in this population. Further, BAPAC undoubtedly accounted for the high rate of discharge home with parents in this study population. This outcome contrasts markedly with experience from high-prevalence urban areas where HIV-risk infants have been abandoned in large public hospitals.<sup>21</sup>

#### *Informed Consent and Pretest Counseling— How Much Does the Woman Understand?*

Our study indicates that current informed consent procedures do not ensure that a woman understands the test's medical implications or socioeconomic risks. In any setting, ethical informed consent requires that a competent person select or reject a recommended procedure or treatment after understanding all reasonable risks associated with that therapy and alternative procedures. Informed consent for newborn care is complicated, however, requiring a proxy decision maker, usually one or both parents. Conflict may arise when an infant's physicians, the parent, and, in some instances, the state disagree about what is best for the newborn. The situation is further complicated in the case of HIV cord blood testing because the test, ostensibly an evaluation of the infant's blood, actually provides information about the woman's HIV status.

As long as seropositivity generates a highly charged social response, a woman's individual circumstances may reasonably warrant an estimation of risk that outweighs the current medical benefits of the HIV-antibody test,<sup>18</sup> and our current refusal rate of 9% for cord blood testing may be an understandable, if not optimal, result. With the future promise of earlier intervention and a broadened spectrum of antiretroviral agents, the precarious balance of rights between the proxy-mother and her infant may increasingly favor testing.

In addition to these structural issues, our results raise concerns about the process of HIV counseling and testing. Why were these women unable to reiterate the meaning of HIV cord blood testing? There are several possibilities. First, postpartum pain, analgesia, and other clinical factors may profoundly compromise information transfer during the postpartum hospital stay. Second, the physicians' effectiveness in communicating may be less than optimal. Postnatal HIV testing may be especially problematic when conducted by the infant's physician because the pediatrician is focused primarily on the infant's medical needs and may not accurately assess its mother's understanding. The HIV cord blood test is relatively difficult to comprehend, and the concept of maternal antibodies implying the possibility of infection in the newborn is abstract. It is notable, however, that the

women counseled by the attending physician were consistently more able to accurately identify the test's medical meaning and socioeconomic risks than were those counseled by the house staff.

The simplest explanation for these women's decisions to accept testing without fully understanding the test's implications may be that they had little to lose. The women positive for the HIV antibody are largely women of color who are unemployed and on Medicaid; they have been referred for testing because of a history of injecting drugs, physical abuse, psychiatric problems, homelessness, or a partner's risk behavior. A positive test result cannot remove financial and social advantages that were never present. Less visible forms of discrimination, especially by family and friends, are more difficult to measure, yet they may have a much greater effect on the fabric of these women's lives. In our study and others, the women expressed concern primarily about the repercussions of a positive test result on their relationships—anger or alienation from their partners, parents, or other family members.<sup>22</sup>

The observation that 78% of those tested did not return to learn their test results is evidence of a failure of the current counseling and testing system to engage women at high risk for HIV infection in a comprehensive HIV prevention and care plan. Certainly this result could imply that the women, after deliberation, chose not to learn of their results in an effort to avoid the psychological or social consequences of known seropositivity. Most of them, however, indicated that they perceived few or no risks associated with the HIV-antibody test, suggesting that other factors played a role in their failure to return for test results. Maternal understanding could be improved by several strategies, such as improved house staff training in informed consent and HIV counseling, HIV counseling conducted by nonphysician counselors, and aggressive follow-up of all women tested to provide posttest counseling. Another opportunity for improved follow-up counseling is prompt availability of results, enabling serostatus determination and counseling to occur before a woman's discharge.<sup>23</sup> Test counseling will also be more straightforward when a diagnostic test capable of determining a newborn's viral status becomes widely available.<sup>24,25</sup>

#### *Perinatal HIV-Antibody Testing Policy— Unanswered Questions*

Although most public and private health organizations agree that testing, counseling, and treatment programs should be offered to pregnant and postpartum women, questions remain about the appropriate type of testing for these women. Some groups have suggested routine perinatal HIV screening programs on the grounds that targeted testing is discriminatory.<sup>4</sup> False-positive results in such a large, low-prevalence population would be costly, however, absorbing funding that could be used in more effective ways. Future introductions of improved infant HIV treatment or cures may mandate a routine approach to HIV-antibody screening for both pregnant and postpartum women.

Offering voluntary HIV-antibody testing of women and children at risk through written informed consent remains the most ethical and practical method for testing.<sup>5</sup> Knowledge of the mother's and infant's serostatus is important in providing optimal care and social support for a family. This information should not, however, be obtained against a woman's wishes or without her understanding.

Our results raise many questions about the ethics of the current informed consent procedures for HIV antibody testing: Why do women fail to understand the test's meaning and risks after giving written informed consent? What kinds of intervention might improve the outcomes? What are the psychological, social, and economic effects of a positive test result on a woman? Will seropositive infants suffer adverse consequences when their families or health care professionals learn of their serostatus? Before advocating and financing more screening, we need to define and implement procedures that meet the policy's goals.

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